lands expiring during the calendar years 1949 through 1978. Orders of the Secretary of the Interior issued pursuant to authority delegated by Executive Order No. 10250 of June 5, 1951, as amended by Executive Order No. 10732 of October 10, 1957, have in recent years, been issued at five year intervals.

APPENDIX TO CHAPTER I—EXTENSION OF TRUST OR RESTRICTED STATUS OF CERTAIN INDIAN LANDS

Trust Periods Expiring During Calendar Years 1979 Through 1983, Inclusive.

By virtue of and pursuant to the authority delegated by Executive Order No. 10250 of June 5, 1951, as amended by Executive Order No. 10732 of October 10, 1957, and pursuant to section 5 of the Act of February 8, 1887 (24 Stat. 388, 389), the Act of June 21, 1906 (34 Stat. 325, 326), and the Act of March 2, 1917 (39 Stat. 969, 976), and other applicable provisions of law, it is hereby ordered that the periods of trust or other restrictions against alienation contained in any patent applying to Indian lands, whether of a tribal or individual status, which, unless extended, would expire during the calendar years 1979 through 1983, inclusive, be, and the same are hereby extended until January 1, 1984.

This order is not intended to apply to any case in which Congress has specifically reserved to itself authority to extend that period of trust on tribal or individual Indian lands.

CECIL D. ANDRUS,
Secretary.

NOVEMBER 24, 1978.

[FR Doc. 78-34771 Filed 12-13-78; 8:45 am]

[4810-31-M]

Title 27—Alcohol, Tobacco Products and Firearms

CHAPTER I—BUREAU OF ALCOHOL, TOBACCO, AND FIREARMS, DEPARTMENT OF THE TREASURY

[T.D. ATF-54]

PART 211—DISTRIBUTION AND USE OF DENATURED ALCOHOL AND RUM

Redenaturation of Recovered Spirits on User Premises Without Supervision

AGENCY: Bureau of Alcohol, Tobacco and Firearms.

ACTION: Final rule (Treasury decision).

SUMMARY: This document deletes the requirement for assigning an ATF officer to supervise the redenaturation of recovered denatured alcohol or specially denatured rum on user premises. The amended regulations will allow supervision to be optional. The specific changes made by this document are discussed below under "Supplementary Information."

EFFECTIVE DATE: January 15, 1979.

FOR FURTHER INFORMATION CONTACT:

Edward J. Sheehan, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226, 202-566-7626.

SUPPLEMENTARY INFORMATION: This final rule is being issued in keeping with ATF's policy of implementing regulations that will pose the least administrative burden to industry members while providing the most protection to Federal revenues and to consumers.

The current regulations in 27 CFR 211.213, 211.214 and 211.216 require ATF supervision for redenaturation of recovered spirits at the premises of a denatured alcohol or specially denatured rum user. Based on an internal review of the regulations, the Bureau concludes that the regional regulatory administrator can determine whether Government supervision will be required for redenaturation of recovered spirits on SDA user premises. Upon implementation of this final rule, the requirement for assigning an ATF officer is at the option of the regional regulatory administrator.

This final rule, also, redesignates existing Form 1483, Redenaturation of Recovered Denatured Alcohol or Specially Denatured Rum, as Form 5110.34 to conform with the Bureau's standard subject classification system.

These regulations will provide manpower savings to the Government, be more convenient for industry, and improve the quality of our regulation of industry. Removal of government supervision for the recovery and restoration of denatured distilled spirits will not result in increased costs to manufacturers.

DRAFTING INFORMATION

The principal author of this document is Edward J. Sheehan of the Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms. However, personnel from other offices of the Bureau and from the Treasury Department participated in developing the document, both on matters of substance and style.

ISSUANCE

Because this Treasury decision is liberalizing, operates to the benefit of the regulated industry and requires no public initiative, it is found to be unnecessary to issue this Treasury decision with notice and public procedure under 5 U.S.C. 553(b).

Except as otherwise noted, these regulations are issued under the authority contained in 26 U.S.C. 7805 (68A Stat. 917).

Accordingly, 27 CFR Part 211 is amended as follows:

1. The table of sections to 27 CFR Part 211 is amended to read as follows:

PART 211—DISTRIBUTION AND USE OF DENATURED ALCOHOL AND RUM

* * * * *

Subpart K—Recovery of Denatured Alcohol, Specially Denatured

* * * * *

Sec.
211.213 * * *
211.214 Redenaturation of recovered spirits.
211.215 Denaturants.
211.216 [Revoked].
211.217 Shipment for restoration or redenaturation.
211.218 * * *

* * * * *

2. Section 211.213 is amended to make ATF supervision optional for the redenaturation of recovered denatured alcohol or specially denatured rum. As amended, § 211.213 reads as follows:

§ 211.213 Reuse of recovered spirits.

(a) If the denatured alcohol or specially denatured rum is recovered in its original denatured state, or practically so, or contains substantial quantities of the original denaturants and other ingredients which render it unfit for beverage or internal human medicinal use, it may be reused in any approved process without further redenaturation. The regional regulatory administrator shall require samples of the recovered product to be taken from time to time for the purpose of determining whether the product requires redenaturation.

(b) If the denatured alcohol or specially denatured rum is not recovered in its original denatured state, or does not contain substantial quantities of the original denaturants and other ingredients which render it unfit for beverage or internal human medicinal use, it shall be redenatured at the premises of the manufacturer or a denaturer before being used. The regional regulatory administrator may require an ATF officer to supervise the redenaturation of recovered spirits.

(Sec. 201, Pub. L. 85-859, 72 Stat. 1372, as amended (26 U.S.C. 5273))

3. Section 211.214 is amended to make ATF supervision optional for the redenaturation of recovered denatured alcohol or specially denatured rum. As amended, § 211.214 reads as follows:

§ 211.214 Redenaturation of recovered spirits.

(a) A manufacturer desiring to redenature on his premises recovered denatured spirits shall submit Form 5150.34, Redenaturation of Recovered Denatured Alcohol or Specially Denatured Rum, to the regional regulatory administrator.

(b) The regional regulatory administrator may approve Form 5150.34 authorizing the manufacturer to redenature the recovered denatured alcohol or specially denatured rum with or without the supervision of an ATF officer.

(c) In accordance with the regional regulatory administrator's approval, the manufacturer shall redenature the recovered spirits by adding the proper quantity of denaturants to meet the requirements of the formula and thoroughly mix the denaturants with the spirits. After redenaturation of the recovered spirits, the manufacturer shall complete Form 5150.34 in accordance with the instructions on the form.

§ 211.216 [Revoked]

4. Section 211.216 is revoked.

Signed: November 9, 1978.

JOHN G. KROGMAN,
Acting Director.

Approved: November 30, 1978.

RICHARD J. DAVIS,
Assistant Secretary (Enforcement and Operations).

[FR Doc. 78-34818 Filed 12-13-78; 8:45 am]

[4110-35-M]

Title 42—Public Health

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Reimbursement for Organ Procurement and Histocompatibility Testing and for Home Dialysis Equipment

AGENCY: Health Care Financing Administration (HCFA), HEW.

ACTION: Final rule with comment period.

SUMMARY: This regulation amends the Medicare regulations for the End Stage Renal Disease program by:

1. Establishing procedures for reasonable cost reimbursement of organ procurement and histocompatibility testing; and

2. Providing for optional 100% reimbursement of the reasonable cost incurred by providers or facilities to purchase, install, maintain and recondition equipment to be used in home dialysis.

The regulation is necessary to implement certain provisions of the End Stage Renal Disease Program Amendments of 1978 (Pub. L. 95-292). The purpose is to specify the rules for cost-based reimbursement.

DATES: This regulation is effective as of October 1, 1978. However, we will consider written comments received by February 12, 1979, with a view to making any necessary changes.

ADDRESSES: Address comments to: Administrator, Health Care Financing Administration, Department of Health, Education, and Welfare, P.O. Box 2372, Washington, D.C. 20012.

When commenting, please refer to file code MAB-80-RC. Agencies and organizations are requested to submit their comments in duplicate. Comments will be available for public inspection, beginning approximately 2 weeks after publication, in Room 5231 of the Department's offices at 330 C Street, S.W., Washington, D.C., on Monday through Friday of each week, from 8:30 a.m. to 5 p.m. (telephone 202-245-0950).

FOR FURTHER INFORMATION CONTACT:

Mr. Hugh McConville, Medicare Bureau, Health Care Financing Administration, Room 412, East Building, 6401 Security Boulevard, Baltimore, Md. 21234, (301) 594-9430.

SUPPLEMENTARY INFORMATION:

BACKGROUND

The Social Security Amendments of 1972 (Pub. L. 92-603) provided Medicare coverage for kidney transplant and dialysis services furnished to entitled individuals suffering from end-stage renal disease. After reviewing the operation of the ESRD program since its inception in 1973, the Congress enacted the End-Stage Renal Disease Program Amendments of 1978 (Pub. L. 95-292) to improve certain features of the program. A major objective of these amendments is to encourage the use of home dialysis and transplantation, the least expensive forms of ESRD treatment.

This regulation implements two provisions of Pub. L. 95-292—one requiring that organ procurement agencies and histocompatibility laboratories be reimbursed under Medicare on a cost basis and the other authorizing 100% reimbursement for home dialysis equipment. It is the fourth in a series of regulations implementing Pub. L. 95-292. The first, amending the Medicare regulations on beneficiary entitlement, was published on September 29, 1978 (43 FR 44802). The second amended the requirements ESRD providers and facilities must meet in order to be certified. It was published on October 19, 1978 (43 FR 48948). The third deals with Medicare coverage of ESRD benefits and was published on October 24, 1978 (43 FR 49720). There will be at least two more regulations implementing Pub. L. 95-292 after this one.

MAJOR PROVISIONS

A. ORGAN PROCUREMENT AGENCIES AND HISTOCOMPATIBILITY LABORATORIES

There are two basic methods for treating patients with kidney failure, through dialysis or transplant of a kidney. The repetitive nature of dialysis treatments in high cost institutional settings has placed emphasis on encouraging transplants whenever possible. In most kidney transplants, a hospital needs the services of two additional organizations—an organ procurement agency and a histocompatibility laboratory—to obtain kidneys from donors and to obtain information needed to insure compatibility between the donor and the recipient.

At the present time, services furnished by such organizations, if they are not part of the transplant hospital, are billed to hospitals, which pay the charges shown on the bill. The charges then become allowable costs of the hospitals. Transplant hospitals have no authority or basis for determining the reasonableness of the charges made by the organ procurement agency (OPA) or the histocompatibility laboratory. Moreover, at present the charge made by the OPA or laboratory is not reviewed by the Medicare intermediary to determine whether it is excessive. The potential, therefore, exists that the Medicare program is paying too much for these services.

Congress dealt with this situation in Pub. L. 95-292 by requiring that reimbursement for the services of OPA's and histocompatibility laboratories in procuring and furnishing organs for transplantation shall not exceed the cost actually incurred by that agency or laboratory. (See section 1881(b)(2)(A) of the Act, 42 U.S.C. 1395rr(b)(2)(A).)

The legislative history of Pub. L. 95-292 indicates that Congress intended

for the Secretary to apply already established principles of cost reimbursement, obtain periodic cost reports, and provide for an intermediary hearing for an agency or laboratory which disagrees with a cost determination. (See S. Rep. No. 95-714, 95th Cong., 2d Sess., 12-13 (1978); H. Rep. No. 95-549, 95th Cong., 1st Sess., 14 (1977).) It is further evident that Congress expected that the cost of these services would continue to be reimbursed through the hospital, but that the Secretary would be authorized to institute a system whereby agencies and laboratories could be reimbursed directly if such a system seems appropriate. We are implementing section 1881(b)(2)(A) and this legislative intent as follows:

1. Reasonable Cost Reimbursement

For services furnished after September 30, 1978 by organ procurement agencies and histocompatibility laboratories, the Medicare program will reimburse only the reasonable cost of these services. In order to do this, the Medicare fiscal intermediaries must obtain cost information from the OPA's and laboratories.

No change will be necessary in the methods for determining the reasonable cost of services provided by a hospital-based OPA or hospital-based histocompatibility laboratory, since their services are currently included in the hospital's cost report and are reimbursed based upon reasonable cost. The current procedures for establishing interim payments and filing and auditing a cost report will remain the same.

However, the procedures for reimbursing OPA's and histocompatibility laboratories that are independent of a hospital will have to be changed, since they have not previously been required to supply cost information or been reimbursed based upon reasonable cost. The absence of such cost information in the past also means that a new mechanism will be necessary to establish an initial interim reimbursement rate in order to maintain the cash flow to such agencies and laboratories prior to the submission and review of their first cost report.

2. Definitions

For the purpose of this provision, an organ procurement agency has the same definition as that specified in 42 CFR § 405.2102(q). A histocompatibility laboratory is a laboratory meeting standards and providing the services set forth in 42 CFR § 405.2171(d). An organ procurement agency or a histocompatibility laboratory is "independent", for purposes of this provision, *unless* it

(i) Performs services exclusively for one hospital; and

(ii) Is subject to the control of the hospital in regard to the hiring, firing, training and paying of employees; and

(iii) Is considered as a department of the hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

3. Reimbursement Mechanism

Services of independent organ procurement agencies and histocompatibility laboratories furnished after September 30, 1978 will be reimbursed in the following way. Any independent OPA or laboratory wishing to receive Medicare reimbursement must sign an agreement with the Secretary, as described in part 4, below. For each kidney transplant performed on a Medicare beneficiary, the transplanting hospital shall receive a prescribed amount of reimbursement from Medicare for the pretransplantation services of an OPA or laboratory having such an agreement. The OPA or laboratory will receive its reimbursement from the hospital. The amount paid to the hospital is an interim reimbursement rate and is subject to a reconciliation based on a final cost report.

An interim rate shall be established by a Medicare intermediary for each agency or laboratory at the beginning of its fiscal year. This rate shall be the average cost per service incurred by that agency or laboratory during its prior fiscal year associated with procuring an organ for transplantation. (For those agencies and laboratories which do not currently have cost data for this purpose, the initial interim rate will be based on a statement of projected costs. However, once an independent OPA or histocompatibility laboratory has filed its first cost report, the interim rate for the services provided by that agency or laboratory will be based upon the previous year's cost report, adjusted if necessary for anticipated changes in costs.)

Once this interim reimbursement rate has been established by the intermediary, it will be disseminated to all transplant hospitals and all other intermediaries, so they will know how much the hospital should be reimbursed. The interim reimbursement rate for any OPA or histocompatibility laboratory may be adjusted by the intermediary during a cost reporting period, if the agency or laboratory submits evidence showing to the intermediary's satisfaction that its actual costs in providing covered services are or will be higher than the interim rate which has been computed. The intermediary may also adjust the interim reimbursement rate if it has evidence that actual costs may fall significantly below the computed rate.

Any independent OPA or laboratory which has an agreement with the Secretary must file a cost report within three months after the end of each fiscal year. (For agencies and laboratories currently being reimbursed under Medicare, and wishing to remain in the program, the first cost report will be due for the first fiscal year ending after September 30, 1978, and will cover the period from October 1, 1978, to the end of the fiscal year.) A cost report must provide a complete accounting of the cost incurred by the agency or laboratory in providing covered services, the total number of Medicare beneficiaries for whom services were furnished by the agency or laboratory, and any other necessary data to enable the intermediary to determine the reasonable cost of covered services to Medicare beneficiaries. The cost report would have to conform to existing regulations on data and accounting requirements for provider cost reports (42 CFR 405.453(a)-(e)).

These cost reports will be handled by the intermediary in the same way other provider cost reports are handled. As quickly as possible, the retroactive adjustment, if any, will be made in the total payments for the cost reporting period and a new interim rate will be determined for the succeeding reporting period. For this purpose, costs will be accepted as reported, unless there are obvious errors or inconsistencies, subject to later audit. When an audit is completed, any further adjustments will be made.

If the intermediary determines that the interim rate payments exceeded the reasonable cost of the services furnished, then the OPA or histocompatibility laboratory must pay the excess amount per Medicare patient to the intermediary. If the intermediary determines that the interim rate payments to the hospital was less than the reasonable cost per service, then an additional amount will be paid directly to the agency or laboratory by the intermediary.

4. Required Agreements

Any independent OPA or histocompatibility laboratory that wishes to have the cost of its pretransplant services reimbursed under the Medicare program must file an agreement with the Secretary. Those agencies and laboratories that are currently reimbursed under Medicare, and wish to continue, must file an agreement within 30 days after the effective date of these regulations. These agreements will be made effective as of October 1, 1978.

The agreement will require that the agency or laboratory agree:

(a) to file a cost report within three months after the end of each fiscal year;

(b) to permit the Secretary to designate an intermediary to determine the interim reimbursement rate payable to the transplant hospitals for services furnished by organ procurement agencies and histocompatibility laboratories and to make a determination of reasonable cost based upon the cost report filed by the agency or laboratory;

(c) to provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;

(d) to pay to the Secretary amounts which have been paid by the Secretary to transplant hospitals and which are determined to be in excess of the reasonable cost of the services furnished by the organ procurement agency and histocompatibilty laboratory; and

(e) not to charge any individual for items or services for which such individual is entitled to have payment made under section 1881 of the Act.

5. Appeals

Any OPA or histocompatibility laboratory which disagrees with an intermediary's cost determination shall be entitled to an intermediary hearing, in accordance with the procedures specified in 42 CFR §§405.1811 through 405.1833, if the amount of reimbursement in controversy is $1,000 or more.

B. REIMBURSEMENT FOR HOME DIALYSIS EQUIPMENT

In 1972, over 40 percent of ESRD patients receiving renal dialysis were dialyzing at home. However, by 1976 less than ten percent of dialysis patients used home dialysis. Recognizing that home dialysis is the least costly form of dialysis, Congress included several provisions in Pub. L. 95-292 modifying and extending coverage of home dialysis services. Among them is section 1881(e) of the Act (42 U.S.C. 1395rr(e)), which creates incentives for the purchase of home dialysis equipment. Under the prior statute, Medicare paid beneficiaries (or their assignees) 80 percent of the rental charge or purchase price of the equipment. Because the equipment is very expensive and most patients were not able to afford the large initial expense for their share in buying this equipment, few beneficiaries bought dialysis machines. The total Medicare rental payments for dialysis equipment made over the life of the equipment in some cases amounted to several times its purchase price.

To solve this problem and to encourage home dialysis, section 1881(e) authorizes HCFA to pay 100 percent of the reasonable costs incurred by ESRD facilities, having agreements with HCFA, for purchasing, installing, maintaining, and reconditioning dialysis equipment for beneficiaries dialyzing at home. Thus, the beneficiaries will not be required to pay the usual Medicare deductible and coinsurance amounts, and facilities will not have to seek these amounts from beneficiaries and other payors. This is an optional method of reimbursement, and ESRD facilities may choose between this method or the method currently used. However, in order to make these payments, HCFA must have formal agreements with ESRD facilities, to assure that they meet certain statutory conditions. We are implementing section 1881(e) as follows:

1. Required Agreements Between HCFA and ESRD Facilities

Section 1881(e) requires that HCFA have an agreement with each ESRD provider and facility wishing to be reimbursed under that section. The terms of these agreements are set forth in a new § 405.690 of the regulations and incorporated by reference in a new § 405.438.

These agreements require that a facility make equipment reimbursed under the agreement available only for use by Medicare beneficiaries on home dialysis. Thus, equipment purchased pursuant to an agreement may not be used to furnish institutional dialysis services or be used by home patients who are not Medicare beneficiaries.

After purchasing a machine under an agreement, a facility is required to continue to use the equipment for home-dialyzing beneficiaries for its full operating life. We recognize that a machine purchased under these provisions may be returned to a facility because of a patient's transplantation, return to institutional dialysis, or death. However, as explained below, we have included provisions in the agreement and the regulations designed to ensure that machines for which Medicare has made full reimbursement remain in use to the maximum extent feasible.

The agreement requires that a facility notify HCFA, or an agency designated by HCFA for this purpose, as soon as any machine purchased under agreement ceases to be used by home-dialyzing beneficiaries. This notification must include the type, brand, and model of the machine, the identification number affixed to the machine by the facility or manufacturer and the reason it is no longer in use. This notification will allow HCFA or its designee to keep current data on machines purchased by Medicare and available for use by home dialysis beneficiaries.

The agreement also requires that before purchasing new equipment, a facility make reasonable efforts to locate a machine or used machine that is suitable for the beneficiary. Before purchasing new equipment, ESRD facilities would be expected to contact HCFA or its designee to try to locate suitable and available equipment. ESRD facilities would also have to examine any equipment they own, but is not in current use, to determine if it could economically be reconditioned to make it suitable for the home dialysis patient. These provisions are intended to ensure that machines purchased under agreements are used economically and effectively and to prevent unnecessary purchases of this expensive equipment.

Facilities must also agree to recover and recondition equipment for reuse throughout its operating life. Facilities are required to maintain equipment so as to assure its availability to beneficiaries during this time and to continue to use equipment so long as it is adequate for the medical needs of home beneficiaries. To further assure continuous use of equipment by beneficiaries, the facility or provider must agree not to subject equipment to liens or other encumbrances and must obtain adequate insurance coverage on the equipment.

The remaining provisions of the agreement require that a facility distinctively identify equipment, keep complete records relating to the purchase and continued use of the equipment, and give HCFA access to all such information. In addition, each facility must agree to submit such reports data and information as HCFA may require with respect to the cost, management and use of the equipment.

2. Ownership of Equipment

Section 405.438 provides that HCFA will reimburse providers and facilities that have agreements with HCFA for the full reasonable cost of purchasing, installing, maintenance, and reconditioning of home dealysis equipment. The regulation provides that ownership of this equipment is vested in the facility which purchases it. However, if a facility has on hand unused equipment purchased under this section, it may transfer ownership of the equipment to another facility having an agreement with HCFA. The transferring facility must notify HCFA or its designee of equipment transfers. Notification under this section and notification required from facilities and providers by their agreements (see § 405.690(a)(6)) will provide HCFA with necessary data on the ongoing use and management of equipment purchased under this section.

Section 405.438 also specifies that if a provider or facility terminates its agreement with HCFA or uses equipment in contravention of the terms of the agreement, HCFA may either direct the facility to transfer ownership of the equipment to another fa-

cility having an agreement with HCFA or may require the facility to repay the program the fair market value of the equipment. We believe this provision is necessary to implement the statute's requirement that equipment be used exclusively for home-dialyzing beneficiaries and to prevent diversion of equipment purchased under this section from use by home beneficiaries at the expense of the program.

HCFA will determine the fair market value of used home dialysis equipment for purposes of this regulation. Usually fair market value is the price at which bona fide sales of similar assets have been made. However, since Medicare is virtually the sole payor of costs of dialysis equipment, an independent, competitive market for this equipment does not exist. Thus, meaningful market data on sales of equipment will probably be unavailable. Under these circumstances, HCFA will develop its own data to approximate the value of used equipment.

3. Computation of Allowable Cost

Costs for purchase, installation, maintenance, and reconditioning of equipment will be accumulated in a separate cost center on Medicare cost reports. Current Medicare regulations for determining allowable cost will apply, as relevant, to limit reimbursement for equipment purchased pursuant to agreements. For example, payment must be based on the reasonable cost of covered services related to the care of beneficiaries (see 42 CFR § 405.451). Discounts and allowances received on the purchase and servicing of equipment are treated as reductions to cost (see § 405.425). Goods or services provided to ESRD facilities by related organizations are included in allowable cost at the cost of the related organization (see § 405.427). Interest paid on borrowed funds will be allowed (see § 405.419). However, since Medicare will pay the full reasonable cost of equipment in a lump-sum payment, the regulation specifically provides that no allowance for depreciation (see § 405.415) may be taken on equipment purchased under agreements, and that the cost of such equipment cannot be used in the computation of equity capital (§ 405.429).

The regulation also provides that Medicare reimbursement will be made only for equipment that is sufficient to meet the medical needs of the patient and that is neither excessive nor extravagant. Reimbursement may not be made for equipment which is substantially more expensive than a medically appropriate alternative. Amounts attributable to machine features of an aesthetic nature or to features of a medical nature that are not required by a patient's condition will not be reimbursed. These rules necessarily require some judgments on the part of Medicare intermediaries, using guidance furnished by HCFA, in determining whether costs are reasonable. In seeking payment under these regulations, facilities must identify the type of equipment purchased as well as the cost and specifications of the equipment. If the intermediary determines that the equipment is excessive or extravagant, the facility will be paid only that amount which would have been paid by a prudent buyer for medically appropriate equipment generally in use for home dialysis patients. Payment will be made for more expensive or specialized equipment only if a physician certifies that such equipment is medically necessary for treatment of the condition of the particular patient for whom the machine was purchased.

The statute recognizes that used and reconditioned machines are suitable for use by home dialyzing patients. Accordingly, this regulation includes specific rules for reimbursement to ESRD facilities for purchase of used equipment. These rules specifically cover facility purchase of machines formerly in use by home beneficiaries under lease agreements, as well as purchase of machines which have been used to furnish institutional dialysis and are made available for used by home beneficiaries. However, the regulation prohibits reimbursement under this method of payment for the purchase of equipment that has been used for institutional dialysis for five years or more. We have adopted this measure because of our concern that such equipment may not be suitable for extended use by a person dialyzing at home and our concern that we will not be able to establish a reasonable approximation of its fair market value.

A facility may be reimbursed under this provision for equipment that it already owns and has been leasing to a home dialysis patient. In this instance, the reimbursable amount may not exceed the lower of the original price of the equipment less the total lease payments already made on the equipment or the fair market value of the equipment on the date it requested reimbursement. If a facility purchases equipment that was owned by someone else and had been leased to a home dialysis patient, the reimbursement under this method may not exceed the lower of the fair market value at the time of purchase or the cost of purchase in accordance with any terms specified in the lease. With respect to equipment previously used in institutional dialysis, for which Medicare reimbursement was made on a cost or cost-related basis, reimbursement under this method may not exceed the lower of the net book value of the equipment or the fair market value on the date reimbursement is requested.

4. Conforming Changes

We are also amending sections 405.544 and 405.601 to conform those sections to the new sections being added. We have also taken the opportunity to redraft section 405.544, without other substantive changes, in order to make it clearer.

WAIVER OF PROPOSED RULEMAKING; EFFECTIVE DATE

Pub. L. 95-292 was enacted on June 13, 1978. Both of the provisions being implemented by this action—sections 1181(b)(2)(A) and 1881(e)—became effective October 1, 1978. Because of the short time between enactment and the legislative effective date, we were unable to publish these regulations as a notice of proposed rulemaking. Moreover, we believe that it is particularly important to implement the liberalized payment provisions of section 1881(e), allowing full reimbursement to providers and facilities and relieving beneficiaries of liability for the 20 percent coinsurance amount, as quickly as possible. Accordingly, we find that good cause exists to waive the notice of proposed rulemaking and not to have a delayed effective date. Recognizing, however, that the full reimbursement option is both new and dissimilar from current Part B payment mechanisms, we invite comments on these regulations, which we will consider in making any future amendments to these regulations.

For both of the provisions being implemented by this amendment, we will make agreements effective as of October 1, 1978 in order to implement the statute properly and avoid adverse impact on people who relied in good faith on the statute.

42 CFR Part 405 is amended as follows:

1. Section 405.436 is added to read as follows:

§ 405.436 Reimbursement of independent organ procurement agencies and histocompatibility laboratories

(a) *Principle.* Covered services furnished after September 30, 1978 by organ procurement agencies (OPA's) and histocompatibility laboratories in connection with kidney acquisition and transplantation will be reimbursed under the principles for determining reasonable cost contained in this subpart. Services furnished by independent OPA's and histocompatibility laboratories, that have an agreement with the Secretary in accordance with paragraph (c) of this section, will be reimbursed by making an interim payment to the transplant hospitals using these services and by making a retroactive

adjustment, directly with the OPA or laboratory, based upon a cost report filed by the OPA or laboratory. (The reasonable costs of services furnished by hospital based OPA's or laboratories will be reimbursed in accordance with the principles contained in §§ 405.405 and 405.454.)

(b) *Definitions.* For purposes of this section:

(1) "Organ procurement agency" means an organization that meets the definition in § 405.2102(q).

(2) "Histocompatibility laboratory" means a laboratory meeting the standards and providing the services set forth in § 405.2171(d).

(3) "Independent"—An organ procurement agency or a histocompatibility laboratory is independent unless it:

(i) Performs services exclusively for one hospital; and

(ii) Is subject to the control of the hospital in regard to the hiring, firing, training and paying of employees; and

(iii) Is considered as a department of the hospital for insurance purposes (including malpractice insurance, general liability insurance, worker's compensation insurance, and employee retirement insurance).

(c) *Agreements with independent OPA's and laboratories.* (1) Any independent OPA or histocompatibility laboratory that wishes to have the cost of its pretransplant services reimbursed under the Medicare program must file an agreement with the Secretary, under which the OPA or laboratory agrees:

(i) to file a cost report in accordance with § 405.453(f) within three months after the end of each fiscal year;

(ii) to permit the Secretary to designate an intermediary to determine the interim reimbursement rate payable to the transplant hospitals for services provided by the OPA or laboratory and to make a determination of reasonable cost based upon the cost report filed by the OPA or laboratory;

(iii) to provide such budget or cost projection information as may be required to establish an initial interim reimbursement rate;

(iv) to pay to the Secretary amounts that have been paid by the Secretary to transplant hospitals and which are determined to be in excess of the reasonable cost of the services provided by the OPA or laboratory; and

(v) not to charge any individual for items or services for which that individual is entitled to have payment made under section 1881 of the Act.

(2) An independent OPA or histocompatibility laboratory whose services were being reimbursed under Medicare on October 1, 1978 and that wishes to continue being reimbursed under Medicare must file an agreement by [30 days after the date of publication].

(3) The initial cost report due from an OPA or laboratory shall be for its first fiscal year ending after September 30, 1978, during any portion of which it had an agreement with the Secretary under paragraph (c) of this section. The initial cost report shall cover only the period covered by the agreement.

(d) *Interim reimbursement.* (1) Hospitals eligible to receive Medicare reimbursement for renal transplantation will be paid for the pretransplantation services of an independent OPA or histocompatibility laboratory, that has an agreement with the Secretary under paragraph (c) of this section, on the basis of an interim rate established by an intermediary for that OPA or laboratory.

(2) The interim rate shall be based on the average cost per service incurred by an OPA or laboratory, during its previous fiscal year, associated with procuring a kidney for transplantation. This interim rate may be adjusted if necessary for anticipated cost changes. If there is not adequate cost data to determine the initial interim rate, it will be determined according to the OPA's or laboratory's estimate of its projected costs for the fiscal year.

(3) Payments made on the basis of the interim rate will be reconciled directly with the OPA or laboratory after the close of its fiscal year, in accordance with paragraph (e) of this section.

(4) Information on the interim rate for all independent OPA's and histocompatibility laboratories shall be disseminated to all transplant hospitals and intermediaries.

(e) *Retroactive adjustment.* (1) *Cost reports.* Information provided in cost reports by independent organ procurement agencies and histocompatibility laboratories must meet the requirements for cost data and cost finding specified in § 405.453(a)-(e). These cost reports must provide a complete accounting of the cost incurred by the agency or laboratory in providing covered services, the total number of Medicare beneficiaries who received those services, and any other data necessary to enable the intermediary to make a determination of the reasonable cost of covered services provided to Medicare beneficiaries.

(2) *Audit and adjustment.* A cost report submitted by an independent OPA or histocompatibility laboratory will be reviewed by the intermediary and a new interim reimbursement rate for the succeeding fiscal year will be established based upon this review. A retroactive adjustment in the amount paid under the interim rate will be made in accordance with § 405.454(f). If the determination of reasonable cost reveals an overpayment or underpayment resulting from the interim reimbursement rate paid to transplant hospitals, a lump sum adjustment shall be made directly between the intermediary and the OPA or laboratory.

(f) *Appeals.* Any OPA or histocompatibility laboratory that disagrees with an intermediary's cost determination under this section shall be entitled to an intermediary hearing, in accordance with the procedures contained in §§ 405.1811 through 405.1833, if the amount in controversy is $1,000 or more.

2. Section 405.438 is added to read as follows:

§ 405.438 Reasonable cost for purchase, installation, maintenance and reconditioning of home dialysis equipment furnished under agreement by providers and dialysis facilities.

(a) *Principle.* Effective October 1, 1978, approved providers of services and renal dialysis facilities that have an agreement with HCFA under § 405.690 of this part will be reimbursed under Part B of Medicare for the full reasonable cost (without regard to the deductible and co-insurance) of the purchase, installation, maintenance, and reconditioning for subsequent use of artificial kidney and automated peritoneal dialysis machines, including supportive equipment (see 405.231 (p)), which are used exclusively by beneficiaries dialyzing at home.

(b) *Ownership of Equipment.* (1) Ownership of dialysis equipment purchased under this section is vested in the provider or renal dialysis facility that purchased the equipment. However, if a facility owns equipment purchased under this section that is not expected to be used in the immediate future, the facility may transfer ownership of the equipment to another facility, having an agreement with HCFA under this section, for use by home-dialyzing beneficiaries. The transferring facility must give notice of the transfer to HCFA or its designee.

(2) If an agreement with a provider or facility is terminated (see § 405.690(b)) or if a provider or facility ceases to use equipment purchased under the agreement in accordance with the terms of the agreement, HCFA will either recover the current fair market value of the equipment (as determined by HCFA) or direct the facility to transfer ownership of the equipment to another facility having an agreement with HCFA.

(c) *Computation of allowable cost.* (1) All costs attributable to purchase, installation, maintenance, and reconditioning of dialysis equipment under

this section must be accumulated in a separate cost center designated on the cost report of the provider or facility.

(2) The facility must use prudent and sound business practices in the purchase of equipment under this section.

(3) Allowable cost for purchase of equipment under this section includes costs for equipment that is medically appropriate for treatment of the particular patient for whom it is purchased and that is neither excessive nor extravagant. Amounts attributable to equipment features of an aesthetic nature or of a medical nature not required by the patient's condition are not allowable. Costs of specialized equipment purchased are allowable only if a physician has certified that such equipment is medically necessary for treatment of a particular beneficiary.

(4) Determinations of allowable costs associated with equipment purchased under this section will be made in accordance with the applicable principles of reimbursement of this subpart.

(5) No allowance for depreciation may be taken on equipment purchased under this section (see § 405.514).

(6) The cost of equipment purchased under this section cannot be used in the computation of equity capital (see § 405.429).

(7) If the equipment is used at the time of purchase, allowable cost shall not exceed the lesser of the fair market value of the equipment on the date of purchase (as determined by HCFA) or the amount calculated as follows:

(i) If the provider or facility owned and leased the equipment to beneficiaries dialyzing at home prior to October 1, 1978 the original cost of the equipment less the total lease payments already received by the facility for such equipment;

(ii) If the equipment was leased by a beneficiary for home dialysis from a person or corporation other than a provider or facility owning the equipment, the cost of purchase in accordance with the terms, if any, specified in the lease, or

(iii) If equipment has been used for institutional dialysis by a facility reimbursed on a cost or cost-related basis, the book value of the equipment. However, payment will not be made under this section for purchase of equipment used in institutional dialysis for five years or more.

3. Section 405.544 is revised to read as follows:

§ 405.544 Payment for durable medical equipment and supplies for home dialysis.

(a) Providers of services that furnish durable medical equipment are reimbursed on a reasonable cost basis in accordance with Subpart D of this part. Renal dialysis facilities having agreements with HCFA for purchase, installation, maintenance, and reconditioning of home dialysis equipment are also reimbursed on a reasonable cost basis in accordance with § 405.438.

(b) When other suppliers furnish durable medical equipment and supplies necessary for home dialysis, payment shall be made on a reasonable charge basis in accordance with § 405.502(a) through (d). However, if the suppliers and the facility which furnishes support services agree to have the supplies routed through that facility, the reimbursement for the necessary supplies will be made to the facility on a reasonable cost basis.

4. Section 405.601 is revised to read as follows:

§ 405.601 Scope of subpart.

The provisions of §§ 405.602–405.626 discuss provider agreements which an eligible provider of services must file with the Secretary in order to qualify for participation in the health insurance program for the aged. Sections 405.651–405.663 and §§ 405.670–405.678 discuss agreements under which Part A intermediaries and Part B carriers will perform specified functions necessary in the administration of the hospital insurance and supplementary medical insurance programs. Section 405.685 discusses agreements which the Secretary shall enter into with any State for the purpose of assisting the Secretary in determining whether an institution or agency situated in such State is a hospital, skilled nursing facility, or home health agency, and whether an independent laboratory meets the conditions for coverage of services, or whether a clinic, rehabilitation agency or public health agency meets the requirements of section 1861(p)(4). Section 405.690 discusses agreements that HCFA will enter into with approved providers of services and renal dialysis facilities for full reimbursement of the reasonable cost of purchase, installation, maintenance, and reconditioning of home dialysis equipment.

5. Section 405.690 is added to read as follows:

§ 405.690 Agreements with ESRD facilities for reimbursement of home dialysis equipment without regard to deductibles and coinsurance.

As provided by section 1881(e) of the Act and section 405.438 of this part, HCFA may make agreements with approved ESRD providers and facilities to reimburse them for the reasonable cost of furnishing home dialysis equipment and supplies specified in § 405.231(p)(1), without regard to deductible and coinsurance provisions of this part.

(a) *Terms of agreement.* The terms of these agreements require that the facility agree to:

(1) Make the equipment available for use only by Medicare beneficiaries dialyzing at home;

(2) Show that it is purchasing the equipment for a patient in dialysis training who is expected to dialyze himself at home;

(3) If the manufacturer or supplier has not done so, inscribe, or attach by plate, a distinctive identification number on the equipment;

(4) Show, for each machine purchase, that, prior to purchase, it made reasonable efforts to locate equipment that was suitable and available for use by home beneficiaries or to adapt available equipment where adaptation is more economical than purchasing new equipment;

(5) Recover and recondition the equipment, as appropriate, for reuse by beneficiaries throughout the operating life of the equipment, including modification of the equipment consistent with advances in research and technology to make the equipment suitable for the intended beneficiary.

(6) Notify HCFA, or its designee, when equipment purchased under the agreement ceases to be used in accordance with the terms of the agreement and comply with directions from HCFA regarding disposition of equipment;

(7) Keep equipment purchased under the agreement free from any liens or other encumbrances and carry adequate insurance thereon;

(8) Keep complete financial records and other information relating to the purchase, maintenance, and use of the equipment, and provide HCFA full access to these records and information;

(9) Submit such reports, data, and information as HCFA may require with respect to the cost, management, and use of the equipment.

(b) *Termination of agreement.* (1) *Termination by the facility.* An ESRD facility having an agreement with HCFA under this section may terminate the agreement after giving notice to HCFA, making a final accounting for all equipment purchased under its agreement, and complying with directions from HCFA regarding disposition of the equipment (see § 405.438(b)(2)).

(2) *Termination by HCFA.* If HCFA finds that a facility has failed to perform its obligations under paragraph (a) of this section, HCFA may terminate its agreement with the facility. HCFA will notify the facility of its intention to terminate the agreement and state the reasons for the termination. The facility will be given the op-

portunity to submit a statement and evidence as to why the agreement should not be terminated. If no statement or evidence is received within 30 days after the date of notification, the termination will be effectuated. At that time, the facility must make a final accounting for all equipment purchased under its agreement and comply with directions from HCFA regarding the disposition of equipment so purchased (see § 405.438(b)(2)).

(Sections 1102, 1814(b), 1833, 1861(v)(1), 1871, and 1881 of the Social Security Act; 42 U.S.C. 1302, 1395f, 1395l, 1395x(v)(1), 1395hh, and 1395rr.)

(Catalog of Federal Domestic Assistance Program No. 13.773 Medicare—Hospital Insurance and No. 13.774, Medicare—Supplementary Medical Insurance.)

Dated: November 13, 1978.

LEONARD D. SCHAEFFER,
Administrator, Health Care Financing Administration.

Approved: November 30, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary.

[FR Doc. 78-34683 Filed 12-13-78; 8:45 am]

[1505-01-M]

Title 45—Public Welfare

SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL ADMINISTRATION

PART 64—MUSEUM SERVICES PROGRAM

Final Rules

Correction

In FR Doc. 78-27284, appearing at page 45166 in the issue of Friday, September 29, 1978 §§ 64.15-64.20 were inadvertently printed twice and the duplicate sections should be deleted.

[1505-01-M]

CHAPTER X—COMMUNITY SERVICES ADMINISTRATION

[CSA Instruction 6802—3a]

PART 1068—GRANTEE FINANCIAL MANAGEMENT

Subpart—Non-Federal Share Requirements for Title II, Sections 221, 222(a) and 231 Programs

Correction

In FR Doc. 78-31760 appearing on page 52438 in the issue of Thursday, November 9, 1978, on page 52445, after the entry under "Seattle", the center heading was inadvertently omitted. It should have been included to read as follows:

APPENDIX C—COUNTIES WITH 24.5%—35% LOW-INCOME FAMILIES (1970)

REGION	STATE	COUNTY	% OF FAMILIES BELOW LOW-INCOME LEVEL

[7035-01-M]

Title 49—Transportation

CHAPTER X—INTERSTATE COMMERCE COMMISSION

PART 1048—COMMERCIAL ZONES

Waiver of Accounting and Reporting Requirements for Certain Class I and Class II Motor Carriers of Property

AGENCY: Interstate Commerce Commission.

ACTION: Notice.

SUMMARY: The Commission's Bureau of Accounts is announcing by this Notice that it will consider requests for relief from the Class I and Class II accounting and reporting regulations for motor carriers of property which operate principally within the boundaries of their commercial zone. The objective of our granting relief from the reporting and/or accounting regulations to such carriers is to relieve the burden on the carrier and to reduce the paperwork burden on the Commission.

ADDRESSES: Submit written requests to Mr. Bryan Brown, Jr., Chief, Section of Accounting, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT:

Bryan Brown, Jr. Tel: (202) 275-7448.

SUPPLEMENTARY INFORMATION:

As a result of the expanded exempt commercial zones in Ex Parte 37 (Sub-No. 26), effective April 9, 1977, a large portion of some carriers' revenues changed from intercity-to local. Many shorthaul carriers whose transportation service is performed principally within their commercial zone will now have practically all local revenue. Since the Commission is primarily interested in the data furnished by carriers for intercity operations, the reporting burden placed on these carriers outweighs the benefits derived from the limited intercity data included in Class I and Class II reports by carriers in this category. The Commission, Accounting and Valuation Board, has allowed a number of carriers to file Class III reports, regardless of total operating revenues, when the circumstances warranted.

The Bureau of Accounts has established a policy to grant relief for carriers operating principally within exempt commercial zones. The objective of our granting relief from the reporting and/or accounting regulations to such carriers is to relieve the burden on the carrier and to reduce the paperwork burden on the Commission. Carriers in this situation may request relief from the accounting and reporting regulations applicable to Class I and Class II carriers. Carriers desiring such relief should submit their request with the following information:

(1) Estimated revenues from intercity operations during current year (Accounts 3100, 3200, and 3400, for I-27 and I-28A carriers), or estimated revenues from intercity household goods operations during current year (Subdivisions of the 3000 series of accounts under activities 1, Interstate, and 2, Intrastate for (I-28B carriers);

(2) Estimated revenues from local cartage service during current year (Account 3300 for all carriers);

(3) Total estimated carrier operating revenues.

Carriers who are granted relief will be required to file annual report form M-3.

Dated: December 11, 1978.

JAMES B. THOMAS, Jr.,
Director, Bureau of Accounts.

[FR Doc. 78-34653 Filed 12-13-78; 8:45 am]